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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,508	02/05/2004	Richard S. Ginn	704117.4012	6546

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EXAMINER

SCHILLINGER, ANN M

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 11/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/773,508

Applicant(s)

GINN, RICHARD S.

Examiner

Ann Schillinger

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>2/5/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character “42” has been used to designate both “tip” on page 13 and “heel” on page 14. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

Claim 3 recites the limitation "the accessing step" in line 1; and the limitation “the wrapping step” in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an

international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4 and 9-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Kuslich (U.S. Pat. No. 6,712,853). Kuslich discloses claim 1 as follows: a method for treating a ruptured or degenerated spinal disc of a patient, comprising: accessing an area adjacent an exterior of a spinal disc disposed between adjacent vertebrae (col. 9, lines 4-14); and wrapping a band of material (12) around the disc to stabilize the disc in a desired position relative to surrounding anatomy (col. 3, line 67 through col. 4, line 2; col. 9, lines 62-67).

Kuslich discloses claim 2 as follows: the method of claim 1, wherein the band engages at least one of the vertebrae when the band is wrapped around the disc to substantially secure the disc relative to the at least one of the vertebrae (shown in Figure 5).

Kuslich discloses claim 3 as follows: the method of claim 1, wherein the accessing step comprises accessing an anterior region of the disc (col. 4, lines 7-10 describes accessing the annulus area of the vertebrae which constitutes the upper portion of the vertebral disc), and wherein the wrapping step comprises: extending a distal end of an elongate member (52) along a first lateral region of the disc around a posterior region of the disc to an opposite second lateral region of the disc (col. 8, line 66 through col. 9, line 1); connecting a first end of the band to the distal end of the elongate member (col. 8, line 60-63); pulling the elongate member back around the posterior region of the disc, thereby directing the first end of the band around the posterior region of the disc (col. 8, line 66 through col. 9, line 1); and securing at least one of the first end and a second end of the band to another portion of the band, thereby securing the band around the disc (col. 9, lines 57-61).

Kuslich discloses claim 4 as follows: the method of claim 1, further comprising adjusting a location of at least one of the vertebrae relative to the disc (col. 9, lines 34-36).

Kuslich discloses claim 9 as follows: the method of claim 1, wherein the band comprises healing-promoting material for enhancing healing of damage to an annulus fibrosis of the disc (col. 10, lines 25-27).

Kuslich discloses claim 10 as follows: the method of claim 1, wherein the band comprises nonporous material, and wherein the band substantially seals any leaks in the disc when the band is wrapped around the disc (col. 9, lines 24-25).

Kuslich discloses claim 11 as follows: the method of claim 1, wherein the band comprises bioabsorbable material that remains around the disc until absorbed by the patient's body (col. 9, lines 19-20).

Kuslich discloses claim 12 as follows: the method claim 1, further comprising applying energy to the disc to enhance healing of the disc (col. 12, lines 48-51).

Kuslich discloses claim 13 as follows: the method of claim 12, wherein at least a portion of the band is electrically conductive (81, 83, 85), wherein the method further comprises coupling a source of electrical energy (95) to the electrically conductive portion of the band (col. 12, lines 54-57), and wherein the applying energy step comprises applying electrical energy to the disc via the electrically conductive portion of the band (col. 12, lines 57-60).

Art Unit: 3738

Kuslich discloses claim 14 as follows: the method of claim 12, wherein the applying energy step comprises applying electrical energy directly to one or more desired regions of the disc (col. 12, lines 57-60).

Kuslich discloses claim 15 as follows: the method of claim 1, further comprising inserting a tubular guide member (52) around a portion of the exterior of the disc (col. 8, lines 67 through col. 9, line 3), and wherein the wrapping step comprises directing the band (12) through the guide member (shown in Figures 7, 8) to facilitate wrapping the band around a posterior region of the disc.

Kuslich discloses claim 16 as follows: the method of claim 1, further comprising inserting a pair of opposite-hand tubular guide members (50) around opposing lateral regions of the exterior of the disc (col. 8, lines 66 through col. 9, line 4).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuslich. Kuslich does not specifically disclose the position of the guide members as they are used to manipulate the location of the band. However, based on the final position of the band,

Art Unit: 3738

shown in Figure 5, it is implied that the guide members would have to be inserted until the distal ends of the guide members are disposed adjacent a posterior region of the disc, for the band to be placed in such a location.

Kuslich discloses the limitations of claim 18, but one would have to use different embodiments of the reference's claimed invention. Kuslich discloses claim 18 as follows: the method of claim 16, wherein the wrapping step comprises: directing a distal end of an elongate member (65) through lumens of the guide members (where the embodiment of Figure 24 would be used in element 52); connecting a first end of the band to the distal end of the elongate member (shown in Figure 7); and directing the distal end of the elongate member back through the lumens of the guide members to direct the band around the posterior region of the disc (col. 9, lines 1-2).

Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuslich in view of Schneiderman (U.S. Pub. No. 2003/0032965). Kuslich does not disclose the use of a fork member to place traction of the vertebrae and make it easier to insert the band.

Schneiderman teaches such a method, described in claims 5 and 6 as follows: the method of claim 4, wherein the adjusting step comprises: engaging at least one of the vertebrae between tines (106, 108, 116) of a fork member (100); and manipulating the tines between the vertebrae to increase a space between the vertebrae; and the method of claim 4, wherein the adjusting step comprises subjecting the patient to traction (paragraph 0043). Therefore, it would have been

Art Unit: 3738

obvious to one of ordinary skill in the art at the time the invention was made to use this fork member if needed to more easily insert the band into the vertebral region.

Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuslich in view of Belef et al. (U.S. Pub. No. 2002/0147497). Kuslich in col. 4, lines 61-67 and col. 5, lines 5-6, discloses fill material used in conjunction with the prosthetic band to promote bone growth and healing, but the reference does not specifically disclose the fill material as being extra-cellular matrix material. Belef et al. teaches the use of this material in paragraph 0013. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use extra-cellular matrix material as the fill material of the band to promote bone growth and healing in the patient.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Schillinger whose telephone number is (571) 272-6652. The examiner can normally be reached on Mon. thru Fri. 9 a.m. to 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3738

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ann Schillinger
November 6, 2006


ALVIN J. STEWART
PRIMARY EXAMINER